OCT 2 4 2011

K102387

TAB 5

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Submission	**August 9, 2010**
Official Contact / Address of Manufacturing facility	Daniel Helme Chief Operating Officer Mediscope Manufacturing Inc. 2832 NW 22nd Terrace Pompano Beach, FL 33069 Phone: 954-975-9997 Fax: 954-975-0775 dhelme@mediscope-mfg.com
Trade Name	Mediscope Asymmetrical Compression Staple and Accessories
Common/Usual Name	Asymmetrical Compression Staple
Device Classification Name	Staple, Fixation, Bone
Classification Reference	21 CFR 888.3030
Classification	Class II
Appropriate Classification Panel	Orthopedic
Product Code	JDR
Predicate Devices	The device is substantially equivalent to: Wright Medical Compression Staple and Simple Staple (K043059)
Reason for submission	New device

K102387

Device Description

The Mediscope Compression Staple is a single patient use device made of surgical grade stainless steel, designed to provide compression across the fusion site of two bones from the adjacent position.

The design features of the Mediscope Compression Staple are summarized below:

- Manufactured from nickel-free stainless steel
- 5 sizes
- Barbs to prevent back out

Indications for Use

The Mediscope Asymmetrical Compression Staple is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus
treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

Summary of Testing and Conclusion

The Mediscope Asymmetrical Compression Staple has the following similarities to the previously cleared predicate device:

- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same intended use.

Substantial equivalency of the Mediscope Asymmetrical Compression Staple and the Wright Medical Charlotte Staple was proven through testing as outlined in ASTM F564-02 (Standard Specification and Test Methods for Metallic Bone Staples). The following is a list of the tests conducted used to compare the two devices: (1) Elastic Static Bending of Metallic Bone Staples; (2) Constant Amplitude Bending Fatigue Tests of Metallic Bone Staples; and (3) Pull-Out Fixation Strength of Metallic Bone Staples.

Biocompatibility testing was conducted per ISO 10993-1 (2003)(E): "Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing".

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mediscope Manufacturing, Inc.
% Dr. Diane Sudduth
Senior RA & QA Consultant
8282 Shadow Wood Boulevard
Pompano Beach, Florida 33069

OCT 24 2011

Re: K102387
Trade/Device Name: Mediscope Compression Staple and Accessories
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: September 16, 2011
Received: September 19, 2011

Dear Dr. Sudduth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102387

Device Name: Mediscope Asymmetrical Compression Staple and Accessories

The Mediscope Asymmetrical Compression Staple is intended to be used for fixation such as: LisFranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodeses or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102387

p. 1 of 1